

33

15. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the tablet has a hardness in the range of about 8 kp to about 23 kp.

16. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the in vitro dissolution assay is performed placing the tablet in 900 mL 0.4 M potassium phosphate buffer with 37° C.±5° C. with a USP paddle speed of 75 rpm.

17. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the tablet has a pharmacokinetic profile for racemic methylphenidate comprising a single mean plasma concentration peak which is about 4 hours to about 5.25 hours under fasted conditions.

18. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein said tablet comprises the equivalent of 40 mg racemic methylphenidate HCl.

19. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein said tablet comprises the equivalent of 20 mg racemic methylphenidate HCl.

20. A method for treating a patient who has been diagnosed with attention deficit hyperactivity disorder, postural orthostatic tachycardia syndrome, or narcolepsy, said method comprising dosing said patient with an effective amount of a methylphenidate extended release chewable tablet according to claim 1.

21. The method according to claim 20, wherein said patient has attention deficit hyperactivity disorder.

22. The method according to claim 20, wherein the patient swallows the tablet intact.

23. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the methylphenidate plasma concentration, as determined under fasting conditions following a single oral administration of said chewable tablet at a dose equivalent to 40 mg racemic methylphenidate HCl in adults under fasting conditions, has the fasting plasma concentration curve of FIG. 1 from about 0 to about 8 hours.

34

24. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the pharmacokinetic profile for the methylphenidate further comprises an AUC0-3 which is bioequivalent to about 18 ng-hr/mL.

25. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the plasticizer is present in an amount of about 2.5% w/w to about 20% w/w of the barrier coating.

26. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the plasticizer is present in an amount of 2.5% w/w to about 15% w/w of the barrier coating.

27. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coat has an elongation factor of at least about 150% to about 400% as measured by a texture analyzer.

28. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein pharmacokinetic profile for methylphenidate further comprises one or more of an AUC0-3 of the fasting or fed plasma concentration curve of FIG. 1 or an AUC0-4 of the fasting or fed plasma concentration curve of FIG. 1.

29. The extended release racemic methylphenidate chewable tablet according to claim 1, wherein the barrier coating is about 10% by weight to about 40% by weight of the methylphenidate-cation ion exchange resin complex defined in (i) as determined prior to the racemic methylphenidate-cation exchange resin complex being coated with the barrier coating of (ii), wherein the racemic methylphenidate-cation exchange resin is optionally in a matrix which further comprises at least one polymer or copolymer.

30. The extended release racemic methylphenidate chewable tablet according to claim 29, wherein the racemic methylphenidate-cation ion exchange resin complex defined in (i) is in a matrix, wherein at least one polymer or copolymer is hydrophilic.

* * * * *